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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,907	11/02/2001	Subramaniam Srikumaran	UNL 3060.2	7717

321 7590 04/20/2004

SENNIGER POWERS LEAVITT AND ROEDEL  
ONE METROPOLITAN SQUARE  
16TH FLOOR  
ST LOUIS, MO 63102

EXAMINER

LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



**Office Action Summary**

Application No.

10/003,907

Applicant(s)

SRIKUMARAN, SUBRAMANIAM

Examiner

Bao Qun Li

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 22-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |



### **DETAILED ACTION**

Claims 1-39 are pending.

#### ***Response to Amendment***

This is a response to the amendment, paper No. 10, filed 01/23/04. Claim 1 has been amended. Claims 1-39 are pending. Claims 1-21 are considered before the examiner. Claims 22-39 are withdrawn from the consideration.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

This application contains claim 22-39 drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-21 is still rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for eliciting an immune response by using a immune complex comprising a heat shock protein fused or conjugated with a viral antigen protein or viral antigen peptide in vitro or expressed by a cell line, does not reasonably provide enablement for using an immune complex to induce an immune response, wherein the complex comprising at least one heterologous or homologous heat shock protein and a viral epitope generated in vitro and in vivo. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

3. Applicants transverse the rejection and argue that examiner is confusing in vitro and in vivo experimentation with where the epitope/heat shock protein complex is formed. Applicant considers a complex formed inside a living cell to be a complex formed in vivo.



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4. Applicants' argument has been fully considered; however, it is not found persuasive because the in vivo experimentation means that an experiment is done in the living body (See Stedman's Medical Dictionary 27<sup>th</sup> Edition).

5. Moreover, the specification does not teach which 5 to 25 amino acids of an epitope for each pathogenic virus as listed in claims 5 to 8 are.

6. Therefore, it is still concluded that an undue experimentation is still required for a person skill in the art to practice the full scope of the invention. The rejection is maintained.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 2-21 are still rejected under 35 U.S.C. 112, first paragraph on the same ground as stated in the previous Office Action, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

9. Applicants traverse the rejection and submit that the specification teaches that heat shock proteins in combination with bovine viral epitopes are useful for immunizing animals. In particular, the specification teaches that bovine viral epitopes from viruses such as bovine viral diarrhea virus, bovine respiratory syncytial virus, parainfluenza virus III etc. are useful. Even more particular, the present specification teaches that proteins and peptides containing allele-specific peptide motif with 8-10 amino acid fragments may be used. Therefore, a skilled artisan would understand exactly what is encompassed by the written description and the instant claims.

10. Applicants' argument has been fully considered; however, it is not found persuasive because although the specification has in general indicate that a fragment comprising an epitope of 5-25 or 5-15 or 8-10 amino acids of all bovine viral antigen is preferred. It still leaves question about what the structure of these amino acid residues is. More importantly, it does not mean that



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Applicants have a possession for any or all viral antigen comprising 8-10 or 5-25 or 5-15 amino acid residues fused with any or all heat shock protein at the application was filed.

11. As discussed in the previous Office Action that Case law of Eli Lilly indicates that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification contains sufficient information to enable a skilled chemist to produce a particular compound because it gives detailed information on how to produce analogous compounds but it makes no reference to the compound in question, the "written description" requirement has not been met even though the description may be enabling. In the instant case, the claimed invention is directed to use certain antigen fragment comprising a supermotif or allele specific motif with a particular amino acid residues, some of the motifs may be able to be obtained by searching the already published database. However, the specification has made no reference to the structure for all these HSP/epitope complexes with an allele specific peptide motif or supermotif in questions. Therefore, the rejection is maintained.

***Conclusion***

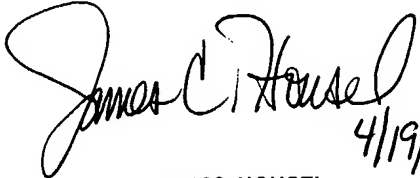
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li  
April 8, 2004

  
JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  
4/19/04